IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL-17-md-2775 Hon. Catherine C. Blake
This Document Relates to Case No. 1:18-cv-590	

COMPLAINT AND JURY DEMAND

This is a product liability lawsuit relating to an artificial metal-on-metal total hip arthroplasty ("THA") system that was never approved for use in U.S. patients, but was nonetheless marketed and promoted to the medical community and the public for almost a decade, causing hundreds of serious injuries in men and women in almost every U.S. state. Plaintiffs, James C. Schalch, Jr. and Angela Schalch, state the following for their specific and general allegations related to the unapproved and fraudulently marketed THA system.

JURISDICTION AND VENUE

1. Plaintiffs, James C. Schalch, Jr. and Angela Schalch, at all times relevant to this action, were citizens and residents of the State of Kentucky with their place of residence located in Maysville, Kentucky, in Mason County, which is part of the Eastern District of Kentucky, U.S. District Court.

2. Defendant Smith & Nephew, Inc. ("Smith & Nephew") is, and at all times relevant to this action was, a corporation organized and existing under the laws of the State of Tennessee, with its principal place of business in Memphis, Tennessee.

3. Complete diversity of citizenship exists pursuant to 28 U.S.C. § 1332. At all times

relevant to this cause of action, Defendant had the requisite minimum contacts with the State of Kentucky, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

4. Plaintiff states and brings this civil action in MDL No. 2775, *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*. Plaintiff is direct filing this Complaint in the District of Maryland pursuant to CMO No. 3, entered by this Court, and pursuant to the Transfer Order of the U.S. Judicial Panel on Multidistrict Litigation of January 31, 2018. But for these orders, Plaintiff's complaint would have been filed in the Eastern District of Kentucky, U.S. District Court.

5. This action arises out of Smith & Nephew's violations of various sections of the Code of Federal Regulations, the common and statutory law of Plaintiff's home state and the damages suffered by Plaintiff as a result thereof.

PLAINTIFF'S INJURIES

6. Plaintiff James C. Schalch, Jr. had a Smith & Nephew BHR resurfacing system implanted in his left hip joint on or about March 25, 2010, by Jonathan Yerasimides, M.D., at Norton Brownsboro Hospital in Louisville, Kentucky. On or about June 1, 2010, Plaintiff had a similar BHR resurfacing system implanted in his right hip by the same surgeon at the same hospital.

7. On or about August 10, 2011, Plaintiff's right resurfacing system failed despite conservative measures and treatment, and Dr. Yerasimedes converted the BHR resurfacing system to a BHR total hip arthroplasty system implanted, including a Synergy stem and modular femoral head.

8. Despite additional conservative treatment and compliance with post-operative recovery guidelines, Plaintiff's left resurfacing system failed due to a pseudotumor and on or about December 1, 2015, Dr. Yerasimedes replaced the resurfacing system, again at Norton Brownsboro Hospital.

9. Plaintiff's saga of failed Smith & Nephew hip systems continued on or about April 24, 2017, when Plaintiff underwent revision of his right BHR total hip system due to pain, pseudotumor and other complications. Plaintiff's revision surgery was again performed by Jonathan Yerasimides, M.D., at Norton Brownsboro Hospital in Louisville, Kentucky.

10. Plaintiff Angela Schalch brings a claim the or loss of consortium.

11. The parties entered into a tolling agreement in 2017 regarding Plaintiffs' claims but were unable to resolve those claims.

12. At the time of Plaintiff's surgeries, neither Plaintiff nor his surgeon were aware of the myriad problems associated with the BHR when used in a THA operation. In fact, Smith & Nephew continued to promote the THA total hip system as a safe alternative to other metal-on-metal hip devices despite the THA not being a safer alternative and not being approved for sale in the U.S.

FACTUAL BACKGROUND

13. Smith & Nephew is a global medical technology company, with its headquarters in England, a presence in more than 90 countries worldwide, and total sales of $4.8 billion in 2017. Its domestic headquarters are in Memphis, Tenn.

14. Defendant markets, manufactures, and sells prosthetic hip devices for use in total hip arthroplasty and resurfacing arthroplasty, specifically the hip socket, acetabulum, and the ball, or femoral head. These hip replacement products include the BHR resurfacing system, which Smith & Nephew withdrew from the U.S. market and subsequently issued a Class II recall on September 10, 2015, due to high failure rates, especially for women. However, Smith & Nephew never issued a recall for the THA "mix and match" system because it was never approved in the first place.

15. Since 2006, Smith & Nephew has manufactured, introduced and/or delivered the BHR and THA into the stream of interstate commerce. The BHR is a metal-on-metal hip resurfacing

prosthesis. It is comprised of a resurfacing femoral head and a matching acetabular cup.

16. The conditional approval letter from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§301, et seq.]."

17. The approval order from the FDA was limited to the acetabular BHR cup used in a resurfacing procedure, and was part of a Premarket Approval application ("PMA") submitted by Smith & Nephew to the FDA. This submission is the most stringent type of application and requires clinical testing and other studies to gauge safety and effectiveness.

18. Plaintiff's initial hip implant surgery included a PMA-approved BHR acetabular cup, but also a modular head and femoral stem that were not approved for use with the cup as part of the above-referenced FDA letter, and all of these components together comprise the THA. Plaintiff's THA was not approved by the FDA, is an off-label use, and does not enjoy any of the protections or recommendations related to the FDA approval for the resurfacing system.

19. Even though the THA total hip system was not approved by the FDA, the decision to implant Defendant's BHR acetabular component with Smith & Nephew's traditional femoral stem, modular head and modular sleeve was based on specific express and implied representations made by Defendant Smith & Nephew to Plaintiff's surgeon and others, including:

a. Marketing materials such as the Smith & Nephew Birmingham Hip Resurfacing System "Metal-on-Metal: Questions & Answers" that expressly states, "If the acetabular component is well positioned, well fixed and undamaged it is totally acceptable to leave the cup in-situ;"

b. Smith & Nephew training provided to Plaintiff's surgeon and his dealings with Smith & Nephew's sales representative that led him to understand that it was permissible to use Defendant's Femoral Component, modular head sleeve and modular Femoral Head **with** Defendant's BHR acetabular component;

c. Smith & Nephew training courses attended by Plaintiff's surgeon that

included written materials and instructional videos that did not advise him that it was not permissible to use Defendant's femoral component, modular head sleeve and modular femoral head **with** Defendant's BHR acetabular component;

d. Defendant Smith & Nephew's sales representative's conduct of bringing Defendant's Femoral Component, Modular Head Sleeve and Modular Femoral Head to total hip arthroplasty and revision procedures on other patients of Plaintiff's surgeon to be available for use leading him to believe that they were safe to use together;

e. Defendant Smith & Nephew's sales representative's conduct of bringing Defendant's Femoral Component, Modular Head Sleeve and Modular Femoral Head to Plaintiff's initial total hip arthroplasty surgery, and without telling the surgeon that said Class II components could not be safely used with the BHR acetabular component; and/or

f. The fact that if Defendant Smith & Nephew's sales representatives had told Plaintiff's surgeon that the Smith & Nephew BHR acetabular component could not be used with the Femoral Stem, Modular Femoral Head and Modular Head Sleeve and that the BHR acetabular component could only be used with the BHR femoral head and that such use was in violation of the PreMarket Approval granted by the FDA, the surgeon would have never used Smith & Nephew's BHR acetabular component in Plaintiff's total hip arthroplasty.

20. Defendant Smith & Nephew's marketing, distribution, training and/or permitted use of its femoral stem, modular head sleeve and modular femoral head with its BHR acetabular cup violate the Federal Food, Drug and Cosmetic Act ("Act"), the regulations promulgated to it and the PMA order granted to Smith & Nephew by the FDA. Specifically, the conduct of Smith & Nephew's sales representatives, including the training it provided to surgeons such as Plaintiff's, and its marketing materials resulted in Plaintiff's surgeon using an unreasonably dangerous device in Plaintiff and a combination of devices which were not approved by the FDA to be used in conjunction with one another.

21. Smith & Nephew's marketing, distribution, training and/or permitted use of its Modular Femoral Head with its BHR acetabular cup also violates, among other things, the modular

femoral head's 510(k) approval by the FDA because the modular femoral heads were only approved for articulation against the natural acetabulum as the intended use, not in a "mix and match" combination with an artificial acetabular cup like the BHR. The 510(k) approval method does not require that the manufacturer prove the safety and efficacy of the device under submission. Rather, this notification is based on the proposed device being "substantially equivalent" to another medical device already on the market pursuant to CFR 807.92(a)(3).[1]

22. The FDA did not approve the combination of these two components, which creates a metal-on-metal articulation, leading to toxic metal ions of cobalt and chromium being released into the patient's body, eventually causing metallosis and other damage to the hip joint. Plaintiff's unapproved total hip system failed because of the metallurgical and biomechanical interaction between all of its metal-on-metal components, due to tens of thousands of natural articulations of the total hip system components over the course of Plaintiff's normal daily activity. The failure of the unapproved total hip system is therefore due to the metal debris generated by the articulation of the 510(k) approved components with the PMA-approved acetabular cup when used together.

23. Because the THA system is not approved by the FDA, its safety and efficacy are difficult to study. However, the system suffers from many of the same problems that plague the BHR resurfacing device, and all metal-on-metal hips, especially in women and in patients with smaller femoral head sizes. For example, a February 2012 article in the Journal of Bone and Joint Surgery revealed the BHR has a 26 percent failure rate in women after ten years, and the authors of the article warned that "results in women have been poor and we do not recommend metal-on-metal resurfacing in women."[2]

[1] The 510(k) Premarket Notification process is described in more detail on the FDA's website. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last visited February 21, 2018).

[2] D.W. Murray, et. al., The Ten-Year Survival of the Birmingham Hip Resurfacing, J. Bone & Joint Surg., 2012;94-B.

24. Plaintiff's THA fails in part because metal ions created by the metal components rubbing together entered the Plaintiffs bloodstream, destroyed tissue, created an adverse reaction and caused the THA to fail and require revision. The metal ions produced by the THA include metal ions from the BHR cup and from the femoral head placed inside that cup.

25. It was the duty of Defendant Smith & Nephew, Inc. to comply with the Act, the regulations promulgated pursuant to it, and the PMA order from the FDA, yet, notwithstanding this duty, Defendant Smith & Nephew violated the Act and the PMA in one or more of the following ways, as evidenced by the conduct described above, among other conduct:

a. Failed to submit a PMA supplement for review and approval by the FDA. 21 C.F.R.§814.39;

b. Defendant Smith & Nephew sold, distributed and permitted use of its devices in violation of the regulations prescribed under 21 U.S.C. §360j(e). 21 U.S.C. § 352(q);

c. Failed to restrict the use of the BHR acetabular cup with the BHR femoral head. 21 U.S.C. §352(r);

d. Failed to comply with the requirements of 21 U.S.C. §§§ 360h, 360i, and 360l;

e. Failed to implement a proper training course for surgeons using the BHR system as required by the PMA Order and in violation of the Act;

f. Failed to properly train surgeons using Defendant's BHR system on the permitted use of the BHR system and its respective component parts and failed to properly train and/or instruct surgeons on what products/devices surgeons could and/or could not use in a total hip arthroplasty; and/or

g. Failed to, among other things, properly train and instruct surgeons on the proper and intended use of the modular femoral head and otherwise comply with the FDA's 510k.

FIRST CLAIM FOR RELIEF – STRICT PRODUCTS LIABILITY

26. Plaintiff herein incorporates, reasserts and realleges the allegations set forth above as

if fully set forth herein below.

27. Defendant designed and/or manufactured the THA system implanted in Plaintiff's hip in violation of the Act and regulations promulgated pursuant to it, as well as the duties created by virtue of the agreements in both the 510(k) and PMA orders related to the various components used in this system.

28. At the time the THA system left the control of Defendant, Smith & Nephew, it was unreasonably dangerous due to Defendant's non-compliance with the Act, in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy, in violation of 21 C.F.R. 820.30(f);

b. Failed to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g);

c. Failed to establish and maintain appropriate reliability assurance testing to validate the THA system design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the THA's latent propensity to effuse metallic contaminants into the human blood and tissue;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the THA system, returned THAs, and other quality problems associated with the THA, in violation of 21 C.F.R. 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the acetabular component was Malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. 820.198;

i. Failed to conduct complete device investigations on returned BHR and components, including the acetabular component, in violation of 21 C.F.R. 820.198; and/or

j. Continued to place the THA into the stream of interstate commerce when it knew, or should have known, that the acetabular component was malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent.

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training.

29. Smith & Nephew's failure to comply with the above-stated requirements is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Smith & Nephew allowed and encouraged its commission-based salesmen to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the THA system but delayed its reporting to the FDA;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise its instructions to doctors and its

surgical techniques documents to reflect the true problematic experience with the THA;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons – both overseas and domestically - upon whose data it relied to boast a high success rate for the THA had been given financial incentives in order to use the THA;

j. Smith & Nephew willfully ignored the existence of numerous complaints about failures associated with components of the THA that were being used in illegal combinations throughout the United States when, in fact, those revision surgeries should have been thoroughly investigated because such usage constitutes an unlawful design change and would provide insight into possible problems that may not be readily seen when the THA system was used as a completed, unaltered system;

k. Smith & Nephew, as a result of increased demand for the product, failed to properly train all surgeons and Original Core Surgeons using the product as required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

l. Smith & Nephew also misrepresented to the surgeons in the United States that in vivo testing of the THA had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable.

m. Smith & Nephew failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the THA system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

30. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a THA system was implanted in Plaintiff's hip, and its subsequent failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained. As a direct and proximate result, Plaintiff endured pain and suffering

and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

31. This cause of action is based entirely on the contention that Defendant, Smith & Nephew violated federal safety statutes and regulations, as well as the conditions established in the Approval Order with which Defendant agreed to comply to obtain premarket approval of the device. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather he is pursuing parallel state law claims based upon Defendant, Smith & Nephew's violations of the applicable federal regulations and Approval Order.

32. Under Kentucky law, Defendant, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

33. Thus, under Kentucky law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries.

34. The Act contains an express preemption provision, 21 U.S.C. §360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§301, et seq.]."

35. However, the cause of action set forth here is not preempted by 21 U.S.C. §306(k)

because the THA system was not approved for sale in the U.S. under either 510(k) or PMA guidelines, and because the violations alleged here are all based on an exclusively federal statutory and regulatory set of requirements and express agreements with the FDA which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder, and because Plaintiff was injured by metal debris from components that are not subject to express preemption under 21 U.S.C. §360(k).

SECOND CLAIM FOR RELIEF - NEGLIGENCE

36. Plaintiff herein incorporates, reasserts and realleges the allegations set forth above as if fully set forth herein below.

37. The THA system, including the acetabular cup and modular femoral head implanted in Plaintiff, were not approved by the FDA for sale in the U.S., but Smith & Nephew nonetheless negligently promoted and marketed them as being safe for patients such as Plaintiff.

38. The THA system implanted in Plaintiff was negligently designed and/or manufactured and marketed in violation of the Act and regulations promulgated to it.

39. It was the duty of Defendant, Smith & Nephew, Inc. to comply with the Act, as well as the conditions established in the 510(k) and PMA approval orders for the various components, and Smith & Nephew agreed to comply with those requirements.

40. The designer of the BHR acetabular cup, Derek McMinn, stated that the learning curve for the BHR was more than 1,000 surgeries, and Smith & Nephew promoted the BHR to hundreds of U.S. surgeons even though it knew most of them would never perform enough hip resurfacings to master the learning curve. Smith & Nephew never informed the FDA of this steep learning curve for the BHR, and to the extent Smith & Nephew was not aware of this learning curve, the failure to discover this learning curve was in whole or in part because Smith & Nephew failed to

carry out the PMA conditions requiring a surgeon training program and a study of the surgeon training program.

41. As a direct and proximate result of Smith & Nephew's aforementioned actions, Plaintiff was injured by a Class III medical device that was never approved by the FDA for sale to surgeons and Plaintiff.

THIRD CLAIM FOR RELIEF – BREACH OF EXPRESS WARRANTY

42. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

43. Smith & Nephew warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the THA system was of merchantable quality, fit for the ordinary purposes and uses for which it was sold, and that its components could be used together in a safe and effective way when in fact they were not safe and effective and were not approved for sale in the U.S.

44. Defendant expressly warranted to Plaintiff, by and through its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the general public, that the BHR system and its "mix and match" components were safe, effective, fit and proper for their intended use, even though they were not approved for sale in the first place in that combination.

45. The Defendant is aware that health care providers and patients, including the Plaintiff, rely upon the representations made by Smith & Nephew when choosing, selecting and purchasing its products, including the THA system products.

46. Due to the defective and unreasonably dangerous and unapproved THA system products, it was neither of merchantable quality nor fit for the particular purposes for which it was

sold, presenting an unreasonable risk of injury to patients, including Plaintiff, during foreseeable use.

47. Smith & Nephew breached its warranty of the mechanical soundness of the BHR system by continuing sales and marketing campaigns highlighting the safety and efficacy of its product, while Defendant knew or should have known of the defects and risk of product failure and resulting patient injuries.

48. Defendant made numerous claims to the general public, and to Plaintiff in particular, that the BHR devices were safe for their intended use and that they did not suffer from the same problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary. For example, almost one year before Plaintiff's initial surgery, Defendant's senior vice president publicly touted the BHR as being "unlike any other metal-on-metal hip implant" with a survivorship rate superior to even traditional non-metal devices due to its "distinctive metallurgy heritage" and other factors.[3]

49. As recently as January, 2015, Defendant referred patients with questions about the BHR devices to a website, www.surfacehippy.com, with claims about people with the BHR devices who completed extraordinary physical feats after implantation, including a "sprint triathlon" with their prosthetic BHR devices.[4]

50. The designer of the BHR acetabular cup, Derek McMinn, stated that the learning curve for the BHR was more than 1,000 surgeries, and Smith & Nephew promoted the BHR to hundreds of U.S. surgeons even though it knew most of them would never perform enough hip

[3] Smith & Nephew, Press Release, *New Clinical Results Further Distance the BIRMINGHAM HIP Resurfacing System from Failed Metal-on-Metal Hip Implants*, February 9, 2012. Smith & Nephew published similar press releases on its Web site on Dec. 7, 2007, and again on May 4, 2010.

[4] See Patricia Walter, *MPH's Hip Resurfacing with Mr. Shimmin*, available at http://www.surfacehippy.info/hipresurfacing/hip-stories/additional-stories/760-mph-s-hip-resurfacing-with-mr-shimmin-2015 (describing a BHR recipient who completed a triathlon in December 2014, exactly 11 months after being implanted with a BHR); the website has been promoted to Smith & Nephew patients by company executives, including but not limited to Tunja Carter, Senior Clinical Affairs Specialist.

resurfacings to master the learning curve. Smith & Nephew never informed the FDA of this steep learning curve for the BHR, and to the extent Smith & Nephew was not aware of this learning curve, the failure to discover this learning curve was in whole or in part because Smith & Nephew failed to carry out the PMA conditions requiring a surgeon training program and a study of the surgeon training program.

51. Pursuant to 21 U.S.C. §360k, the above statements constitute a violation of the PMA because the FDA's conditional approval of the BHR devices warned Defendant that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws."

52. The defective and unreasonably dangerous condition of the BHR products also constituted a breach of the Defendant's express warranties under Kentucky law, in part because the THA system device was never approved by the FDA for sale in the configuration in which it was implanted in Plaintiff, even though Smith & Nephew led surgeons and patients to believe it was approved and was safe.

53. As a direct and proximate result of Defendant's breaches of express warranties, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

FOURTH CLAIM FOR RELIEF – BREACH OF IMPLIED WARRANTY

54. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

55. Defendant impliedly warranted that the THA system was merchantable and was fit for the particular purposes for which they were intended.

56. Defendant had reason to know the particular purpose for which its BHR products were required, and that Plaintiff was relying on Defendant's skill and judgment to furnish suitable goods. For example, the PMA Letter approving the BHR device noted that it is particularly well suited for younger or more active patients who "may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral hip joint revision."

57. The THA system was not suitable for young and active patients, especially women and those with smaller femoral head sizes, and unlike the BHR resurfacing cup the total hip system did not receive the scrutiny of the PMA process, and in fact was not approved for sale in the U.S. at all.

58. When the THA system was implanted in Plaintiff to treat Plaintiff's damaged and worn hip joints, Plaintiff and Plaintiff's surgeons reasonably thought that the THA system was being used for the particular purposes for which they were intended, and they were particularly intended for Plaintiff.

59. Plaintiff, individually and/or by and through Plaintiff's healthcare provider, relied upon Defendant's implied warranties of merchantability and fitness for a particular purpose, in consenting to have the THA system implanted, with the hope and expectation that the metal-on-metal device would last longer than a traditional polyethylene or ceramic prosthetic device and thus not require a painful revision surgery.

60. Plaintiff also relied on Smith & Nephew's representations that the THA system was a "bone conserving" device and that it would be a less invasive procedure, when in fact the THA system is not a bone conserving device system at all, and is just as invasive and damaging as other

metal-on-metal hip systems made by competing manufactures such as the DePuy ASR, Zimmer Durom, Biomet M2a Magnum and Wright Conserve, all of which have been removed or recalled from the U.S. market due to premature and catastrophic failure in patients.

61. Defendant breached these implied warranties of merchantability and fitness for a particular purpose because the THA system implanted in Plaintiff was neither merchantable nor suited for the intended uses as warranted, because it carried a high risk of premature failure due to metallosis.

62. Defendant's breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of Plaintiff, placing Plaintiff's health and safety in jeopardy.

63. The above-mentioned violations and failures constitute a parallel violation of Kentucky common law and statutory law that predates and operates independently from the above federal requirements.

64. As a direct and proximate result of Defendant's breaches of these implied warranties, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

FIFTH CLAIM FOR RELIEF – NEGLIGENT MISREPRESENTATION

65. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

66. Defendant had a duty to accurately and truthfully represent to the medical community, Plaintiff, and the public that THA system had not been adequately tested and found to be safe and effective for the treatment of damaged and worn parts of the hip joint. Instead, the representations made by Defendant were false.

67. Smith & Nephew negligently misrepresented to the medical community, Plaintiff, and the public that the THA system did not have a high risk of dangerous adverse side effects.

Defendant made this misrepresentation by consistently underreporting adverse events for both the BHR and for the THA system, delaying reporting of adverse events, and promoting the THA system as if it were a safe and effective medical device approved by the FDA, when in fact it was not approved at all.

68. Smith & Nephew caused physicians, the medical community and the general public to believe that the THA system received the same scrutiny that its BHR cup received in the PMA order, when in fact Smith & Nephew never received any approval for the THA system, which requires a physician to remove the acetabular cup in a revision, even if it is well-fixed to the natural acetabulum, as illustrated in the below warning.

> Currently, in the USA, Smith & Nephew, Inc. does not have a commercially available modular metal femoral head for use with a BHR resurfacing shell. Therefore, if the BHR resurfacing head must be revised to a total hip arthroplasty, the acetabular shell should also be revised, even if well fixed.

69. Had Defendant accurately and truthfully represented to the medical community, Plaintiff, and the public the material facts relating to the risks of the BHR and the THA system, Plaintiff and/or Plaintiff's healthcare providers would not have utilized the BHR or the THA system for Plaintiff's treatment.

70. Defendant effectively deceived and misled the scientific and medical communities and consumers regarding the risks and benefits of the THA system by intentionally and surreptitiously marketing the total hip system as being safe and effective, despite the system never having been approved for use in U.S. patients.

71. The above-mentioned violations and failures constitute a parallel violation of

common law that predates and operates independently from the above federal requirements, and violates both the PMA and 510(k) approval orders for the various components, which carry an unreasonably high risk of premature failure when used in combination with each other.

72. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

SIXTH CLAIM FOR RELIEF – UNFAIR AND DECEPTIVE TRADE PRACTICES

73. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

74. Plaintiff purchased and used Defendant's THA system primarily for personal use and thereby suffered ascertainable losses as a result of Defendant's violations of the PMA Letter for the BHR cup, and the 510(k) approval order for the various other components including the modular femoral head, which constitutes parallel violations under state consumer protection laws.

75. Had Smith & Nephew not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Defendant's unapproved and fraudulently marketed THA system products, and would not have incurred related medical costs and injuries.

76. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiff for the THA system that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

81. Defendant's actions, as complained of herein, and as suppliers, manufacturers, advertisers, and sellers, constitute unfair, unconscionable, deceptive, and/or fraudulent acts or trade practices.

82. As a direct and proximate result of Defendant's unfair and deceptive trade practices, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

SEVENTH CLAIM FOR RELIEF – FRAUDULENT CONCEALMENT

83. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

84. Throughout the relevant time period, Defendant knew that its THA system products were defective and unreasonably unsafe for their intended purpose.

85. Smith & Nephew was under a duty to disclose to Plaintiff and the medical community the defective nature of the THA system products, including the fact that they were not FDA approved, because Smith & Nephew was in a superior position to know the true quality, safety, and efficacy of the THA system products. Defendant fraudulently concealed the danger of the THA system by underreporting adverse events for the BHR and the THA, delaying reporting of adverse events, categorizing them in a way that hid the true risk of failure due to metal-on-metal symptoms, and surreptitiously and intentionally promoting them as if they were FDA approved and safe.

86. Defendant fraudulently concealed from and/or failed to disclose to Plaintiff, Plaintiff's healthcare providers, and the medical community that its BHR resurfacing products and THA system were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

87. The facts concealed and/or not disclosed to Plaintiff and the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize Defendant's BHR resurfacing products and THA system.

88. As a direct and proximate result of Defendant's fraudulent concealment, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint.

EIGHTH CLAIM– NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

89. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

90. Defendant carelessly and negligently manufactured, developed, tested, labeled, marketed, and sold the THA system products to Plaintiff, carelessly and negligently concealing the harmful effects from Plaintiff, and carelessly and negligently misrepresented the quality, safety, and efficacy of the products, in violation of the terms of its PMA Letter and federal regulations, as described in greater detail above.

91. Plaintiff was directly impacted by Defendant's carelessness and negligence in that Plaintiff purchased the BHR products and THA system and has therefore sustained and will continue to sustain emotional distress, physical injuries, economic losses, and other damages.

92. Defendant's actions, as complained of herein, negligently inflicted emotional distress upon the Plaintiff. The above-mentioned violations and failures and failures to comply with federal regulations constitute a parallel violation of common law that predates and operates independently from the above federal requirements, including both the PMA and 510(k) approvals for the various components, which are furthermore not approved to be used in combination with each other. Common law furthermore allows this cause of action on Plaintiff's behalf because the BHR and THA came into contact with his body, and his injuries were severe.

93. As a direct and proximate result of Defendant's negligent infliction of emotional distress, Plaintiff has sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

94. As a direct and proximate result of Defendant Smith & Nephew's improper training and marketing to U.S. surgeons on the implantation of the BHR cup with its modular femoral head and modular head sleeve and femoral stem in violation of one or more of these federal statutory and regular standards, an unreasonably dangerous BHR acetabular cup and an unreasonably dangerous combination of Smith & Nephew products in a THA system which were not approved for use with one another, were implanted in Plaintiff and failed, and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff, as defined in 21 C.F.R. 803.3.

NINTH CLAIM FOR RELIEF – PUNITIVE DAMAGES

95. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

96. The acts and omissions of the Defendant as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Among other things, Smith & Nephew knew that its THA system was not approved for sale in the U.S., but it nonetheless intentionally and surreptitiously marketed the system as being similar to the PMA-approved BHR resurfacing system, even though Smith & Nephew knew that it was not.

97. Because the THA system was not approved by any regulatory agency in the U.S, Smith & Nephew intentionally delayed reporting failures of the system to the FDA, and concealed information about the widespread use of the unapproved system in thousands of patients in almost every state in the U.S. Accordingly, Plaintiff is entitled to an award of punitive damages.

TENTH CLAIM FOR RELIEF – LOSS OF CONSORTIUM

98. Plaintiff incorporates by reference as if fully set forth verbatim each and every allegation in the Complaint.

99. Plaintiff, Angela Schalch, brings a consortium claim for the loss of services, aid, society, conjugal relationship and companionship that she suffered as a result of her husband's hip failures due to Defendant's acts and omissions, and she is entitled to recover damages for same.

WHEREFORE, Plaintiffs pray that this Court enter judgment against the Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), together with pre-judgment and post judgment interest, attorneys' fees and costs of this action as may be recoverable, and for such further relief as this Court deems just and reasonable.

PLAINTIFF DEMANDS A TRIAL BY JURY.

Dated: February 27, 2018

Respectfully submitted,

JONES WARD PLC

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